

Section 5 – 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive P.O. Box 587 Warsaw, IN 46581-0857
Phone number	(574) 372-1941
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Jared Cooper Regulatory Affairs Specialist
Date prepared	09/06/13
Name of device	
Trade or proprietary name	A.L.P.S Calcaneal Plating System
Common or usual name	Bone Fixation Plate
Classification name	Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030)
Classification panel	Orthopedics
Regulation	21 CFR § 888.3030
Product Code(s)	HRS - Plate, Fixation, Bone: Single/multiple component metallic bone fixation appliances and accessories
Legally marketed device(s) to which equivalence is claimed	DePuy Fracture and Fusion Plating System (K093474), DePuy Calcaneal Plate (K993465), Tornier Calcaneal Fracture Plate System (K090582)
Reason for 510(k) submission	New Device Construct
Device description	The new A.L.P.S calcaneal plating system is a series of bone plates and screws intended to stabilize calcaneal fractures. The plates come in a left and right specific MIS configuration with five size options and left and right MESH configuration that is offered in three sizes. The plates are manufactured from titanium (ASTM F136) and will utilize the legally marketed and predicate A.L.P.S screw system.
Indications for use	The Biomet A.L.P.S Calcaneal Plating System is intended for fixation of fractures, fusions, and osteotomies of the calcaneus.
Summary of the Technologies	
The technological characteristics of the A.L.P.S calcaneal plating system are similar to the predicate devices including design, dimensions and material.	

PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
Performance Test Summary-New Device
<p>The A.L.P.S Calcaneal Plating System components have the same basic technological and material characteristics as the predicate devices except for slight modifications to the general design as described in this 510(k) notification. Preclinical performance tests/rationales were provided to address the subject construct's strength. Results indicate that the subject construct is substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.</p>
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
<p>Clinical Performance Data/Information: None provided as a basis for substantial equivalence.</p>
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
<p>The results of preclinical tests/engineering rationales and the similarities with legally marketed devices indicate ALPS calcaneal plating System is substantially equivalent to currently marketed devices. No new issues of safety or efficacy have been raised.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2013

Biomet Manufacturing Corporation
Mr. Jared Cooper
Regulatory Affairs Specialist
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581-0857

Re: K132898

Trade/Device Name: A.L.P.S Calcaneal Plating System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS

Dated: October 1, 2013

Received: October 2, 2013

Dear Mr. Cooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number: K132898

Device Name: **A.L.P.S Calcaneal Plating System**

Indications For Use:

The Biomet A.L.P.S Calcaneal Plating System is intended for fixation of fractures, fusions, and osteotomies of the calcaneus.

Prescription Use **X**
(Per 21 CFR 801 Subpart D)

AND/OR Over-the-Counter _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices